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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,953 12/10/98 FODSTAD

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EXAMINER

HM12/0421

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ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

04/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/125,953

Applicant(s)
Oystein Fodstad et al.

Examiner
Bradley L. Sisson

Group Art Unit
1655



☒ Responsive to communication(s) filed on 13 Mar 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-11 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10 and 11 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See pages 2-4 of the prior Office action for the basis of the rejection.

Response to arguments

At pages 1-3 of the response received 13 March 2000 argument is presented that it is well within the level of skill of an artisan to practice the gene therapy method of claim 10. In support of this position, attention is directed to two journal articles appended to the response. The presence of one or more journal articles does not present convincing evidence to support applicant's position as they have not been prepared and presented as a declaration under 37 CFR 1.132.

At page 2 of the response it appears that agreement is reached in that the method of claims 10 and 11 are directed to, or encompass, gene therapy wherein said gene therapy is targeted to genes which are previously unknown, but identified by using the present method. At page 2, third paragraph, of the response it is stated in part:

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When inventors identify differentially expressed genes; e.g., in a metastatic cell growing in the lung, it may mean that such is facilitated by expression of one or several of the specifically identified genes. The next step would naturally be to attack such a gene by, for example, gene therapy. Such methods are known to the artisans in the field.

While the application of gene therapy may be a “natural” next step, it is anything but a foregone conclusion that any one of the as yet to be identified genes will respond to gene therapy. As has been borne out over the last several years, gene therapy is wrought with obstacles and is highly unpredictable. See the articles of Ross (1996), Verma *et al.*, (1997), Anderson (1998), and Weiss (2000). As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

Clearly, the aspect of gene therapy is highly unpredictable and as such, the level of disclosure needed to satisfy the enablement requirement as set forth under 35 USC 112, first paragraph, need be much greater than that presented in the subject application. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.

At page 2, bridging to page 3, of the response it is asserted that “[o]nce specific gene sequences are identified according to the method of the invention, it is well within the abilities of one of skill in the art to obtain the specific gene sequences and their expression products.”

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The above argument has been fully considered and has not been found to be persuasive towards the withdrawal of the rejection as applicant is unfairly shifting the burden of enablement to the public by requiring the public to discover the new genes, to clone same, to express same and to determine which version of the to be expressed gene product has the as yet to be determined activity that would permit use of the gene product. Clearly, such broad suggestions as found in the subject application do not constitute an enabling disclosure for all types of genes. Further, the specification does not teach how such gene products are to be used. As set forth in 35 USC 112, first paragraph, the specification must enable the making and use of the invention. Accordingly, the specification must enable the use of the product, the expressed product, as well as the method of finding the genes and expressing same. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Høifødt et al.

See the prior Office action for the basis of the rejection.

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Response to argument

At page 4 of the response argument is presented that “[t]he reference does not, however, mention nor suggest gene cloning to study differences in mRNA expression levels by comparison.”

The above argument has been fully considered and has not been found to be persuasive towards the withdrawal of the rejection for at page 7 of the reference the aspect of establishing a clonal colony of certain malignant cells is disclosed. Clearly, the establishment of a clonal colony constitutes “cloning.” Further, the ultimate paragraph at page 7, bridging to page 8, discloses a variety of non-limiting methods used in the analysis of nucleic acid sequences where the cells from which the nucleic acid is obtained are first isolated.

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be


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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on Monday through Thursday from between the hours of 6:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP 1800-1650
4/19/2000